DEC - 9 2004

Section 11 510(k) Device Summary

Canterbury Scientific Ltd
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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is **K043070**

Submitter	Canterbury Scientific Ltd 14 Pope Street Christchurch New Zealand Phone +64 3 343 3345 FAX +64 3 343 3342
Contact Person	Maurice Owen, PhD, Scientific Director
Date of Preparation	November 2, 2004
Device Name	Liquid Stable HbA1c Control
Common Name	HbA1c Controls
Classification	21CFR 862.1660 Quality Control Material (assayed and unassayed)
Class	1
Product Code	JJX
Equivalent Device	Quantimetrix Corporation, GlycoHemosure. (510(k) # K032791)
Description of Device	The Liquid Stable HbA1c Control is a bi-level liquid HbA1c control that is prepared from human red cells. The control should be treated the same as patient specimens and tested following the instructions included with the instrument, kit or reagent being used.
Intended Use of Device	The Liquid Stable HbA1c Control is intended for use as a quality control material to monitor the performance of laboratory testing procedures for HbA1c quantitation. The control is designed for use with Ion exchange HPLC assays, Immunoassay based assays and Boronate Affinity based assays. The use of quality control materials is indicated as an objective assessment of the precision and bias of methods and techniques in use and is an integral part of good laboratory

practices. The two levels of controls allow performance monitoring within the clinical range.

The controls are for in vitro diagnostic use only and should not be used past the expiry date.

Comparison with Predicate Device

The Canterbury Scientific Ltd Liquid Stable HbA1c Control is substantially equivalent to *Glycohemosure HbA1c Control* manufactured by Quantimetrix Corporation. They both have the same intended application and technical characteristics.

Canterbury Scientific Ltd Liquid Stable HbA1c Control has an open vial stability of 30 days at 2°-8°C, the same as Quantimetrix's *Glycohemosure*. The closed vial stabilities are also identical at 18 months at 2° - 8°C.

Performance Characteristics

Stability studies at 20° - 25°C were performed on the Bio-Rad Variant, Bayer DCA200, Roche Hitachi 917 and Primus CLC385 to validate the open vial stability claims. Real-time studies were performed on the Bayer DCA2000 and BioRad Variant at 2°-8°C. The results support a shelf life at 2°-8°C of 18 months and an open vial claim of 30 days (at 2°-8°C).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 9 2004

Maurice Owen, PhD
Scientific Director
Canterbury Scientific Ltd
14 Pope Street
Christchurch 8001
New Zealand

Re: k043070
Trade/Device Name: Liquid Stable HbA1c Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: November 3, 2004
Received: November 8, 2004

Dear Dr. Owen :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043070

Device Name: Liquid Stable HbA1c Control

Indications for Use:

The Liquid Stable Hemoglobin A1c Control is intended for use as a quality control material to monitor the performance of laboratory testing procedures for HbA1c quantitation. The control is designed for use with Ion exchange HPLC assays, Immunoassay based analyses and Boronate Affinity based assays.

The use of quality control materials is indicated as an objective assessment of the precision and bias of methods and techniques in use and is an integral part of good laboratory practices. The two levels of controls allow performance monitoring within the clinical range.

The controls are for *in vitro* diagnostic use only and should not be used past the expiry date.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043070